

PATENT COOPERATION TREATY

Rec'd PCT/PTO 12 JUL 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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File

77359/002

10 NOV 2003

Frank B. Dehn & Co.

ANCD

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Date of mailing

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06.11.2003

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference
27.14.77359/002

REPLY DUE

within 2 month(s)

from the above date of mailing

International application No.
PCT/GB03/00156

International filing date (day/month/year)
16.01.2003

Priority date (day/month/year)
16.01.2002

International Patent Classification (IPC) or both national classification and IPC
C12Q1/68, C12Q1

Applicant
DYNAL BIOTECH ASA et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 16.05.2004

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26/11/04

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I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-53 as originally filed

Claims, Numbers

1-29 as originally filed

Drawings, Sheets

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this opinion.)

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	26,27
Inventive step (IS)	Claims	1-25,28,29
Industrial applicability (IA)	Claims	

2. Citations and explanations**see separate sheet**

Re Item V

The following documents are referred to in this communication:

- D1: WO 00 61806 A
- D2: Nucleic Acids Research (1998) **26(21)** 5007-5008
- D3: DE 4237381 C
- D4: EP 0 885 958 A

1 Novelty (Art 33(2) PCT):

- 1.1 **Claims 26 and 27** are not novel over D3, which discloses a solid support, that binds genotypic (i.e. nucleic acids) and phenotypic (i.e. protein) material in distinct areas (D3: co 1 line 57- col 2 line 8; claims 1-4).
Moreover, numerous materials are known, which bind protein and nucleic acids, e.g. nitrocellulose or nylon. These materials are also novelty destroying for claim 26.
- 1.2 **Claims 1-25, 29** are novel, because none of the available documents discloses a method involving isolating nucleic acid and protein from the same sample wherein nucleic acid and protei are bound to distinct solid supports.
- 1.3 **Claim 28** is novel, because none of the available documents discloses a kit comprising the features of **claims 26 or 27** and the further features contained in **claim 28**.

2 Inventive Step (Art 33(3) PCT):

- 2.1 **Claim 1** is not inventive over D1, which is considered to represent the closest prior art:
D1 discloses the simultaneous detection of HER-2/neu mRNA and protein (Example 2).
Claim 1 is distinguished from the method of D1 in that it requires that nucleic acid and protein components of the same sample become bound to distinct solid supports, whereas according to D1 nucleic acid and protein become bound to different areas of the same solid support.

we allow that!!

The difference between the subject-matter of claim 1 and D1 seems to be a matter of design and does not appear to solve a technical problem. Thus, inventiveness cannot be acknowledged. Moreover, a design as defined in claim 1 is used in the method of D2 (Fig. 1) As the further features contained in dependent **claims 2-25** do not seem to be based on an inventive idea but belong to the standard repertoire of the skilled person (e.g. binding of mRNA to a support by using oligo dT D4: col 11 line 29-38) , said claims are not considered inventive, either.

2.2 **Claim 29** is directed to the use of the method of claim 1, which is also envisaged in D1 (D1: page 2 para 2-4, page 17 para 5). Thus, **claim 29** contravenes Art 33(3) PCT.

2.3 **Claim 28** does not seem to be inventive for the following reasons: The skilled person who wants to economically exploit the method of D2 (abstract, page 5007 col 1 para 3- col 2 para 1, Figure 1) would put together a kit comprising said two solid supports (D2: page 5007 col 1 para 3- col 2 para 1). The kit according to claim 26 does not appear to be inventive over said kit on the basis of the method of D2 (abstract, Figure 1, page 5008 col 1 para 2-col 2 par 1). The same argument applies to the kits defined in **claims 27 and 28**.

3 Clarity/Support (Art 6 PCT):

Claims 26-28 contravene Art 6 PCT, because the scope of the claims as defined by the functional definition "suitable for binding nucleic acids/proteins" is not commensurate with the contribution of the application to the art.

The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/GB03/00156

the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.